SECTION 6: 510(k) SUMMARY

K103050

Submitter:	LeMaitre Vascular, Inc. 63 Second Avenue Burlington, MA 01803 JAN 19 2011
Contact Person:	Andrew Hodgkinson Vice President, Clinical and Regulatory Affairs Phone: 781-221-2266 x108 Fax: 781-425-5049 Email: ahodgkinson@lemaitre.com
Date Prepared:	October 15, 2010
Trade Name:	Albograft™ Vascular Prosthesis
Common Name:	Vascular Prosthesis
Classification Name:	Graft, vascular, synthetic/biologic composite
Predicate Device:	Hemashield Woven Double Velour Vascular Graft (K954848)
Device Description:	Albograft Vascular Prosthesis is a knitted/woven tubular polyester fabric, impregnated with bovine collagen.
Intended Use:	The AlboGraft Double Velour Knitted and Woven Grafts are indicated for use in the replacement or repair of arteries affected with aneurysmal or occlusive disease.
Summary of Technological Characteristics:	AlboGraft Polyester Vascular Prosthesis is a knitted or woven tubular polyester fabric, impregnated with bovine collagen.
Summary of Product Testing:	The following tests have been performed per ISO 7198: *Burst Test* *Longitudinal Tensile Strength* *Radial Tensile Strength* *Suture Pull-90°/45°* *Wall Thickness* *Integral Water Permeability* *Visual Inspection* *Usable Length* *Relaxed Inner Diameter* *Pressurized Inner Diameter*
Summary of Pre-clinical Study:	The biocompatibility of the device was tested per ISO10993-1.
Summary of Retrospective Clinical Review	**Patient baseline data, preoperative risk factors, diagnosis and secondary diseases:** Between Jan 1, 2007 and March 31, 2009, 66 consecutive patients have received a surgical implant of a peripheral AlboGraft™ vascular prosthesis in the iliac region (prox. anastomosis - common iliac artery / distal anastomosis - proximal superficial femoral artery). The patients consisted mainly of males (n= 44 / 66 %) with a mean age of 64.8 years (Mean: H: 171 cm; W: 74 kg; BMI: 25.2 kg/cm²) and demonstrated typical

risk factors for development of iliac artery peripheral arterial occlusive disease (pAOD).
The majority of patients (88%) suffered from arterial hypertension and histories of smoking in 92% of the cases (73% of all patients are still active smokers). Almost half (49 %) of the patients had additional coronary heart disease , while additional risk factors like diabetes mellitus or hyperlipidemia was only present in 9% or 3% of the patients respectively. Chronic obstructive pulmonary disease was present in 29% of the patients and cerebro vascular disease in n= 10 (15%) of which n=8 had a previous stroke. Also almost half of the patients (49%) had previous arterial reconstructions.

Disease / Diagnosis:
4 patient suffered from aneurysmal disease (n=2 iliac artery aneurysms; n=2 suture line aneurysms) and 62 patients reported pAOD of the iliac artery with either severe claudication / Fontaine stage IIb (n=42/68%), rest pain / Fontaine III (n=9/15%) or ulcerations or gangrene / Fontaine stage IV (n=11/18%). (Table 1).
The severity of the iliac artery disease could be confirmed by a mean pain free walking distance of only 89m and a mean Ankle Brachial Index (ABI) on the affected side of 0.46.
Only patients with TASC II C (n=37 / 60%) and TASC II D (n=25 / 40%) classification of disease morphology were operated on.

Operative and postoperative results summary:
The 66 patients received either unilateral bypass reconstructions in n=40 (61%) or a cross-over bypass procedures in n= 26 (39%) of the cases.

30 day mortality was 4.5 % (n=3) and no graft infection has been recorded during the complete follow up period.

Postoperatively the ABI of the affected side improved significantly to 0.89 from 0.46 and the majority of patients were in Fontaine stage I and IIa at their last follow up visit. (Table 1). The primary and secondary patency rates at 12 and 24 month have been 88.9%/95.1 % and 88.9%/95.1% respectively. The Limb Salvage Rate was 98.4% at 12 and 24 month (Table 2).

Table 1: Pre and Post Operative (last follow up visit) Fontaine stage Classification for the n= 62 patients with Peripheral Arterial Disease (pAOD).

Fontaine stage	Pre-Op (n=62)	Last follow up visit (n=57)
I – asymptomatic	0 (0.0%)	39 (62.9%)
IIa- Lifestyle limiting Intermitted Claudication (IC)	0 (0.0%)	11 (17.7%)
IIb – Severe Intermitted Claudication (IC)	42 (67.7%)	7 (11.3%)
III – Restpain	9 (14.5%)	0 (0.0%)
IV – Ulcerations or Gangrene	11 (17.7%)	0 (0.0%)

Table 2: Patency and Limb Salvage Rates in % analyzed by Kaplan Meier Survival Analysis:
n = 66 patients (SE = Standard Error)

	12 month	24 month
Primary Patency Rate	**89.4%** (SE 4%) n = 51 at risk	**89.4%** (SE 4%) n = 19 at risk
Secondary Patency Rate	**95.1%** (SE 2.8%) n = 55 at risk	**95.1%** (SE 2.8%) n = 20 at risk
Limb Salvage Rate	**98.4%** (SE 2.8%) n = 57 at risk	**98.4%** (SE 2.8%) n = 22 at risk

Conclusion:	LeMaitre Vascular has demonstrated that the Albograft Polyester Vascular Prosthesis is substantially equivalent to the predicate device based on its indications for use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LeMaitre Vascular, Inc.
c/o Mr. Andrew Hodgkinson
63 Second Avenue
Burlington, MA 01803

JAN 19 2011

Re: K103080
AlboGraft Double Velour Knitted or Woven Vascular Prosthesis
(Peripheral indication)
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: MAL
Dated: October 18, 2010
Received: October 19, 2010

Dear Mr. Hodgkinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103080

Device Name: LeMaitre AlboGraft Double Velour Knitted or Woven Vascular Prosthesis (peripheral indication)

Indications For Use:

The AlboGraft Double Velour Knitted or Woven Vascular Prosthesis (peripheral indication) are indicated for use in the replacement or repair of arteries affected with aneurismal or occlusive disease.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richmond

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103080